



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 15

[Docket No. FDA-2012-N-1148]

Food and Drug Administration Actions Related to Nicotine Replacement Therapies and Smoking-Cessation Products; Report to Congress on Innovative Products and Treatments for Tobacco Dependence; Public Hearing; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of public hearing; Extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice of public hearing that appeared in the Federal Register of November 28, 2012 (77 FR 70955). In the public hearing notice, FDA requested comments on FDA consideration of applicable approval mechanisms and additional indications for nicotine replacement therapies (NRTs), and input on a report to Congress examining the regulation and development of innovative products and treatments for tobacco dependence. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: Submit either electronic or written comments by January 16, 2013.

ADDRESSES: Submit electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 28, 2012, FDA published a document announcing a public meeting on December 17, 2012, and the opening of a public docket to receive comments related to the implementation of section 918 of the FD&C Act (21 U.S.C. 387r), as amended by the Tobacco Control Act (Public Law 111-31). Under Section 918(a), the Secretary of the Department of Health and Human Services (the Secretary of HHS) is required to consider certain new approval mechanisms and additional indications for NRTs. Several NRTs, including nicotine-containing gums, patches, and lozenges, are already marketed for smoking cessation. Section 918(b) requires that the Secretary of HHS, after consultation with recognized scientific, medical, and public health experts, submit a report to Congress examining how best to regulate, promote, and encourage the development of “innovative products and treatments (including nicotine-based and non-nicotine-based products and treatments)” to better achieve the following three goals: (1) Total abstinence from tobacco use, (2) reductions in consumption of tobacco,

and (3) reductions in the harm associated with continued tobacco use. FDA will consider the information it obtains from the public hearing and related docket submissions in its implementation of the requirements of section 918, including in drafting the report to Congress required by section 918(b).

II. Submission of Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Dated: December 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.